

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Asisaturov, et al.

Appl. No. 10/690,199

Filed: 10/21/2003

For: Vaccines Using High-Dose Cytokines

Confirmation No.: 3672

Art Unit: 1632

Examiner: Wu C.W. Shen

Mail Stop Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**DECLARATION UNDER 37 C.F.R. § 1.131**

I, Neil Berinstein, a citizen of Canada, declare as follows:

1. I am an inventor on the present application ("our application"), together with Igor Astasaturov, Teresa Petrella, Mark DeBenedette, and David E. Spaner.
2. I have been involved in cancer research as Head of the cancer vaccine program at Sanofi Pasteur, and as a clinician-scientist and Professor of Medicine and Immunology at the University of Toronto and Sunnybrook Hospital since 1988. At the time the invention described in our patent application was made, I was an employee of Sanofi Pasteur.
3. I have reviewed the pending claims of our application. Our claims relate to a method for administering to a mammal a composition comprising a nucleic acid encoding melanoma-associated tumor antigen, and subsequently administering to that mammal one or more high doses of interferon alpha 2b (IFN- $\alpha$ 2b). This corresponds with what is described in Examples 1 and 2 of our application.
4. Our U.S. provisional patent application was filed on October 22, 2002. However, we conceived of and began to reduce to practice our claimed invention prior to that date, as described in point 5.
5. I contacted Dr. Patrick J. Halloran, our patent attorney at Sanofi Pasteur, at least as early as July 9, 2002 to describe our invention and discuss the possibility of preparing a patent application. At that time, I submitted a draft manuscript (attached as **Appendix A**) describing our invention to Dr. Halloran.

6. During the entire time between at least July 9, 2002 and the filing date of our patent application, I believe we acted with diligence in developing our invention.
7. All statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application and any patent issuing thereon.

A handwritten signature in black ink, appearing to read "Neil Berinstein". The signature is fluid and cursive, with a horizontal line extending from the middle of the name.

---

Neil Berinstein, M.D.

September 29, 2010

---

Date